

This is an official CDC HEALTH ADVISORY

Distributed via Health Alert Network
Tuesday, February 26, 2008, 20:15 EST (8:15 PM EST)
CDCHAN-00270-2008-02-26-ADV-N

Important Safety Information -- Revised Directions for Using Rabies Immune Globulin (Human), HyperRAB™ S/D in Fixed Needle 2 mL Pre-filled Syringe

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have been notified by Talecris Biotherapeutics, Inc. that its Rabies Immune Globulin (Human), HyperRAB™ S/D in fixed needle 2 mL pre-filled syringe does not address all dosing situations. Specifically, the fixed needle (22 gauge, 1.25 inch) and the absence of graduations on the 2 mL pre-filled syringe do not permit administration of the recommended dose of Rabies Immune Globulin (Human), HyperRAB™ S/D in one or more of the following situations:

- A dose < 2 mL is required (e.g. for pediatric use);
- A dose < 2 mL must be injected over multiple sites; or
- An alternate needle (different length or gauge) is required based on the patient (adult or child), wound or site of injection.

Three lots of HyperRAB™S/D have been manufactured with the 2 mL pre-filled syringe configuration (see Table below):

Lot Number	Expiration Date	Size/Container	NDC Number
26N87R1	Jan-26-2009	2 mL pre-filled syringe	13533-618-03
26N88K1	Jan-26-2009	2 mL pre-filled syringe	13533-618-03
26N9HP1	Feb-18-2010	2 mL pre-filled syringe	13533-618-03

Healthcare providers may continue to administer HyperRAB S/D supplied in the 2 mL pre-filled syringe by following the "Revised Directions for Use" that are packaged with these lots. The full "Revised Directions for Use" of these lots is available on-line: http://www.talecris.com/us/documents/FINAL_FDA_Approved_Revised_Directions_for_Syringe_Use__21-FEB-08.pdf . Talecris has discontinued manufacturing the HyperRAB™S/D fixed needle, 2 mL pre-filled syringe.

For additional information regarding this product, please contact Talecris on-line at www.talecris.com, or call 919-412-1030, or toll free at 1-800-520-2807.

Human rabies PEP (post-exposure prophylaxis) is recommended when potentially infectious material (e.g. saliva) from a rabid animal is introduced via a bite, or comes into direct contact with broken skin or mucous membranes. More detailed information regarding evaluation for and administration of PEP is available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00056176.htm>.

For more information about rabies and its prevention, contact your state or local public health official or CDC at 1-800-CDC-INFO or visit www.cdc.gov/rabies.

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national and international organizations.

DEPARTMENT OF HEALTH AND HUMAN SERVICES